UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,378	02/18/2004	Bruce K. Redding JR.	04-40080-US (879388.20001	3551

7066 7590 07/18/2006

REED SMITH LLP
2500 ONE LIBERTY PLACE
1650 MARKET STREET
PHILADELPHIA, PA 19103

EXAMINER	
GRAY, PHILLIP A	

ART UNIT	PAPER NUMBER
3767	

DATE MAILED: 07/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/782,378	REDDING, BRUCE K.	
	Examiner	Art Unit	
	Phillip Gray	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/4/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to applicant's communication filed on 5/3/2006. Currently claims 1-18 are pending and rejected.

Information Disclosure Statement

The information disclosure statement filed 4/4/2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Specifically pages 3-5, of the Information Disclosure Statement, does not contain a legible copy of the non-patent literature and has not been considered. A previous incorrect IDS was sent that indicated that the non patent literature was considered. A corrected IDS is included and it shows that the pages 3-5 of nonpatent literature has not been considered.

Response to Arguments

Applicant's arguments filed 5/3/2006 have been fully considered but they are not persuasive.

Applicant presented arguments that the Lewis et al. prior art fails to disclose "at least one sensor" positioned with a transducer "to sense reflected ultrasonic transmission". Further applicant argues that the sensing elements of Lewis have

nothing to do with the "sensing of ultrasonic transmissions indicative of substance moving into tissue".

The transducer and sensor of Lewis can be used for medical therapy and thus drive substances through its drive elements (18) from transducer (12) and sense this operation through a sensing element (sensor 20). Therefore Lewis does meet the structural components of "at least one sensor" positioned with a transducer. The applicants argument appears to not be a lack of sensor, but rather that the sensor of lewis could not be used to sense reflected ultrasound transmissions, as specified in the claims

The Lewis sense elements use a piezoelectric effect to generate an electrical signal in response to the mechanical displacement of the drive elements. These mechanical displacements would result in a change in the operational characteristics of the drive elements and the resultant sonic output, and this change would be sensed by element 20. These changes could be changes such as temperature variations, loading, stress cracking or electrical imputs. (see paragraphs at column 3 lines 6-25). Lewis discloses that the sensor element could sense these changes (such as temperature variations, loading, stress cracking or electrical imputs,). These changes could be used to sense ultrasound and be indicative of such detection, and substance moving into tissue. The reflected ultrasound transmissions would indeed make changes to the temperature variations, loading, stress cracking or electrical imputs, and cause the sensing elements to "sense" the reflected ultrasonic transmissions. This would be used to indicate that the substance moved into the tissue".

Additionally Lewis discloses that the sense elements (20) can be used to provide diagnostic or monitoring information regarding the operation and environment of transducer and the transducer working area and to control the driving elements in real time (see paragraphs at column 3 line 25-46). Applicant has no physical, structural, or linguistic limitations in the claims that the sensed reflected ultrasonic transmissions must be a *direct* ultrasound sensing by an ultrasound sensor. Further the claims state of only an indication that substances were actually moved into tissue. There is no requirement that the indication be through direct sensing means.

Simply put, the Lewis device contains all structural components claimed and these elements would be fully capable of performing the intended sensing function of ultrasound transmissions and the indication of substances moved.

In response to applicant's argument that the sensor of Lewis does not sense reflected ultrasonic transmissions indicative of substance moving into tissue, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Applicant presented arguments that the Jackson et al prior art does not disclose a method of transdermal delivery, nor is there a sensor in Jackson that would sense reflected ultrasonic transmissions indicative of substances actually moved into said tissue.

In response to applicant's arguments concerning the Jackson reference lacks a transdermal drug delivery, the recitation "for transdermal substance delivery" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Such is the case with applicant's claim 10. The preamble recites the purpose of the process (drug delivery), and the body of steps in the claim are able to stand alone (transducer and sensor for ultrasound drug delivery). Applicant has given no claim steps of introducing a drug or substance transdermally, delivering a drug or substance transdermally, ect. The only specific claim steps that concern drug delivery is generating an ultrasonic transmission from a transducer for inducing *movement of a substance into tissue* (no details were given as to how the substance/drug got to the tissue). There is no language in the claims about the "transdermal push of substances into a tissue", as in the remarks of the applicant.

The Jackson prior art does disclose a medical diagnostic ultrasound aided drug delivery system and method. Further the drug delivery may be (in one embodiment of Jackson) delivered by injection but (in other embodiments) adjacent to the tissue to be treated. Further Applicant has not included any claim steps about the specific mode of

applying the substance to be delivered to the tissue or transdermal application. Jackson contains all the steps of the claims, generating a signal, positioning a transducer and sensor (discussed below), and sensing ultrasonic transmission.

Concerning applicant's argument that Jackson fails to disclose a sensor for sensing reflected ultrasonic transmission indicative of substance moved into tissue. Examiner draws applicant's attention to the elements 18, and 20. The "receive beamformer" and "scan converter" are the Jackson reference's sensor unit (see paragraphs beginning at column 3 line 16). This sensor unit and step is fully capable of sensing reflected ultrasonic transmissions, such as in B-Mode and Doppler mode, and these images would be indicative of substances moved into the tissues (see paragraph beginning at column 6 line 43). Jackson discloses 1.) an ultrasonic transmission from a transducer for inducing movement (the acoustic destruction of the microbubbles induce movement of the drug substance in the tissue) and 2.) a sensor that may sense reflected ultrasonic transmission indicative of substance moved into tissue (see discussion above). Therefor the Jackson reference meets all claim limitations of claim 10 and contains all the steps required for drug delivery. Applicant has made no claims as to the method, mode, or means of the "transdermal push" of a substance to the tissue. Applicant has merely claimed a set of claim steps that that comprise generating signals, which induce movement, and sensing those transmissions (see discussion above).

Applicant's claims and arguments fail to distinguish applicant's invention over the prior art of record, therefore the rejections are proper.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 6,392,327 (Lewis et al.). Lewis discloses a sonic transducer and feedback control method to provide an ultrasonic output transducer for imaging, medical therapy, motors, and sonar systems. Lewis discloses an apparatus suitable for transdermal substance delivery comprising at least one ultrasonic transducer (12), which generates an ultrasonic transmission, and at least one sensor (20) with at least one transducer to sense reflected ultrasonic transmission (see paragraphs 4 through 6), along with a control device (14). It is noted that the disclosed Lewis apparatus is capable of meeting the functional use recitation of claim 1, thereby Lewis could be used to sense ultrasonic transmissions indicative of substances or drugs moved through tissue or another medium.

Claims 10 and 18 are rejected under 35 U.S.C. 102(a) as being anticipated by U.S. Patent 6,475,148 (Jackson et al.). Jackson discloses a method for ultrasonic transdermal delivery. The Jackson method relates generally to using ultrasound for delivery of drugs from microspheres. In Jackson, diagnostic medical ultrasound imaging was used to image microspheres and destroy them with acoustic energy. The

destruction of the microspheres was optimized such that subsequent imaging showed an inflow or wash-in of new microspheres into the image region or provided a loss of correlation (see column 1, line 28). This method includes a transducer generated ultrasonic transmission for inducing substance movement, a sensor that senses substance movement from reflected ultrasonic transmissions, and a control device (columns 2 through 4).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis in view of Shimada et al. (U.S. Patent number 5,267,985). Lewis discloses the claimed invention except for the ultrasound frequency transmission in the range of about 20 KHz to 30 MHz. Shimada teaches that it is known to use ultrasound frequency transmissions in the range of 1hz to 100 MHz for therapeutic or diagnostic ultrasound, (as set forth in Column 5,Line 39 through Column 7, Line 13) to provide "optimum diffusion of the drug across the stratum corneum while maximizing penetration of a drug or other substance into the local area of target tissue". It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the ultrasonic transducer as taught by Lewis to operate in a 1hz to 100 MHz frequency

range as taught by Shimada, since such a modification would provide the ultrasonic transducer with a 1hz to 100 MHz frequency range to provide for effective and efficient diffusion of drugs into a given tissue.

Claims 3 through 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis in view of Dellagatta (U.S. Patent number 5,954,675). Lewis discloses the claimed invention except for the ultrasonic intensity range and alternating, pulsed, or continuous waveform. Dellagatta teaches that it is known to use an ultrasonic intensity range up to 3.0 W/sq. cm. (Column 3, Line 7) to foster hydration of the stratum corneum (Column 3, Line 47). It would have been obvious of one having ordinary skill in the art at the time the invention was made to modify the ultrasonic transducer as taught by Lewis with a 0 to 3.0 W/sq. cm. intensity range as taught by Dellagatta, since such a modification would provide the ultrasonic transducer with a 0 to 3.0 W/sq. cm. Ultrasonic transmission intensity range for providing hydration of the tissue that is receiving the ultrasonic signals.

Further Dellagatta discloses that it is known to use an alternating, pulsed or continuous waveform (Column 1, Line 14) as a preferred treatment where heat exacerbates pain in the patient, or when only non-thermal, mechanical effects of ultrasound, e.g. enhancement of tissue regeneration, are desired. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the ultrasonic transducer's waveform as taught by Lewis with an alternating, pulsed, or continuous waveform as taught by Dellagatta, since such a modification would provide the transducer's waveform with and alternating, pulsed, or continuous

waveform, for providing treatment without heat and a mechanical therapy for pain management and tissue regeneration.

It is noted that Lewis in view of Dellagatta discloses the claimed invention except for specifically referencing a "sawtooth" waveform or a "square" waveform. It would have been obvious to one having ordinary skill in the art at the time the invention was made that the alternating waveform produced by the ultrasonic transducer included both "square" or "sawtooth" waveforms, since it was known in the art that "square" or "sawtooth" waveforms are typical types of alternating waveforms for enhanced measured efficient ultrasonic transmission delivery.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson (6,475,148) in view of Shimada (5,267,985). Jackson discloses the claimed method except for the ultrasound frequency transmission in the range of about 20 KHz to 30 MHz. Shimada teaches that it is known to use ultrasound frequency transmissions in the range of 1hz to 100 MHz for therapeutic or diagnostic ultrasound, (as set forth in Column 5,Line 39 through Column 7, Line 13) to provide "optimum diffusion of the drug across the stratum corneum while maximizing penetration of a drug or other substance into the local area of target tissue". It would have been obvious to one having ordinary skill in the art at the time the method was made to modify the transdermal substance delivery method as taught by Jackson to operate in a 1hz to 100 MHz frequency range as taught by Shimada, since such a modification would provide the transdermal substance delivery method with a 1hz to 100 MHz frequency range to provide for effective and efficient diffusion of drugs into a given tissue.

Claims 12 through 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson in view of Dellagatta (5,954,675). Jackson discloses the claimed method except for the ultrasonic intensity range and alternating, pulsed, or continuous waveform. Dellagatta teaches that it is known to use an ultrasonic intensity range up to 3.0 W/sq. cm. (Column 3, Line 7) to foster hydration of the stratum corneum (Column 3, Line 47). It would have been obvious of one having ordinary skill in the art at the time the invention was made to modify the transdermal drug delivery method as taught by Jackson with a 0 to 3.0 W/sq. cm. intensity range as taught by Dellagatta, since such a modification would provide the transdermal drug delivery method with a 0 to 3.0 W/sq. cm. Ultrasonic transmission intensity range for providing hydration of the tissue that is receiving the ultrasonic signals.

Further Dellagatta discloses that it is known to use an alternating, pulsed or continuous waveform (Column 1, Line 14) as a preferred treatment where heat exacerbates pain in the patient, or when only non-thermal, mechanical effects of ultrasound, e.g. enhancement of tissue regeneration, are desired. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the transdermal delivery method as taught by Jackson with an alternating, pulsed, or continuous waveform as taught by Dellagatta, since such a modification would provide the transdermal delivery method with and alternating, pulsed, or continuous waveform, for providing treatment without heat and a mechanical therapy for pain management and tissue regeneration.

It is noted that Jackson in view of Dellagatta discloses the claimed invention except for specifically referencing a "sawtooth" waveform or a "square" waveform. It would have been obvious to one having ordinary skill in the art at the time the invention was made that the alternating waveform produced by the method's ultrasonic transducer included both "square" or "sawtooth" waveforms, since it was known in the art that "square" or "sawtooth" waveforms are typical types of alternating waveforms for enhanced measured efficient ultrasonic transmission delivery.

Prior Art of Record

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent Number 5,445,611, Eppstein et al. discloses a method and apparatus for Enhancement of transdermal delivery with ultrasound and chemical enhancers

U.S. Patent Number 6,041,253, Kost et al. discloses a method and apparatus for effect of electrical field and ultrasound for transdermal drug delivery.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571) 272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PAG

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER